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Victor Song

Prof. Peter Hutt
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Introduction

When Watson and Crick discovered the structure of deoxyribose nucleic acid (DNA) in 1953 the science of biotechnology underwent a technological revolution. Since that auspicious event, there have been a great deal of biotechnological advances such as genetically modified organisms, new medical treatments, and the sequencing of the human genome[1]. Following in tandem with these biotechnological breakthroughs is the patent system. The patent system is designed to reward and encourage innovation by granting intellectual property rights to inventors for their inventions. The patent right the government grants to qualified inventions is a limited monopoly in the market. Because the patent's monopoly right is a valuable market opportunity, it is natural for inventors to seek patent protection for their new biotechnology inventions. In fact, the nature of the biotechnology industry with its high research and development costs has made patent protection essential to success.

[1]Edmund J. Sease, *From Microbes, to Corn Seeds, to Oysters, to Mice: Patentability of New Life Forms*, 38 Drake L. Rev. 551 (1999).

Brief Overview of the Patent System

What is a patent?

A patent is a government issued grant to the patent owner for the right to exclude others from making , using, or selling the patented invention. In order for an inventor to obtain a patent he must first submit a patent application to the United States Patent and Trademark Office (USPTO). At the USPTO there are patent examiners who specialize in different arts. The patent examiners are divided into different art groups. Each art group is knowledgeable in a specific area of technology and will examine a patent application falling within her art group. For example, a patent application for a mechanical invention, such as an airplane, will be given to an examiner knowledgeable in the mechanical arts, and not, for example, to a biologist. Upon receiving the patent application, the patent examiner will study the application and determine if the invention has met all the statutory requirements necessary for patentability. If the patent application meets these requirements, the USPTO will issue a patent to the inventor. Upon obtaining the patent, the inventor will have the right to exclude others from making, using, or selling his patented invention for twenty years measured from the date his patent application was filed. United States patents are only valid within the United States. In order for an inventor to obtain patent protection in other jurisdictions, he must file separate applications in each of those jurisdictions. Recently, there has been a movement within the international community to harmonize patent laws to make it easier for inventors to obtain worldwide patent protection.[2] After the patent is issued by the USPTO, the patent is published and is accessible to anyone in the world. A published patent is comprised of several sections, two of which are worth noting. Near the beginning of the patent is the written description. The first part of the written description is the "Background of the Invention" which describes the state of the prior art. The prior art can be best described as the body of

[2]Donald S. Chisum, et al., Principles of Patent Law 5 (1988).

knowledge existing prior to the invention's discovery. The purpose of the "Background of the Invention" is that it sets the stage for the invention by describing the prior art. It also points out the most important aspect of the invention and how it differs from the prior art. Following the "Background of the Invention" is the "Detailed Description". The Detailed Description describes the invention in sufficient detail to enable one skilled in the art to make and use the invention. The inventor must also disclose the best mode of carrying out the invention known to him at the time the patent application was filed. The written description serves to place the invention in the hands of the public and add the knowledge of the invention to the collective knowledge of society. The written description does not demarcate the boundaries of the inventor's property rights, this is the purpose of the claims. [3]

The claims are the second significant section of an issued patent. The claims serve to set forth the metes and bounds of the inventor's right to exclude. Thus, the claims should accurately point out and claim the subject matter of the patented invention. An inventor asserts her claims against an alleged infringer of his patent. A claim is comprised of several elements, each of which describes a particular aspect of the invention. In order for a product to infringe the claim, the product must contain each and every claim element.[4]

Why have patents?

The patent system exists to encourage the development of new inventions and technologies for the benefit of society. The patent system resolves problems inherent with treating inventions as property. The inherent problem with inventions is that they are essentially comprised of information. For example, when Thomas Edison invented the light bulb he gave the world the information about how to transform electricity into

[3]Id. at 79
[4]Id. at 86

light. The problem with information is that it is free for anyone to use. Information has the characteristics of a public good. Public goods are characterized as being nonrival and nonexclusive.

A good is nonrival if consumption by one person does not leave any less of the good to be consumed by others. In the case of Edison's light bulb, the ability of Edison to manufacture light bulbs does not prevent Alexander Graham Bell from manufacturing light bulbs. Both inventors can use the knowledge of the light bulb invention without leaving any less for the other. In fact, an infinite number of manufacturers can use the knowledge of the light bulb. In contrast to a nonrival good would be a rival good. An apple is an example of a rival good. Once it is eaten by Edison, it no longer exists. Bell cannot also eat Edison's apple.

A good is nonexclusive if people cannot be prevented from using it. In the case of Edison's light bulb, once Edison tells the world about his invention he cannot exclude others from using the knowledge of the light bulb invention. Another problem Edison faces is that if he sells his light bulb to the public, a competitor could reverse engineer it and then sell it to the public. The competitor would be able to receive all the profits for selling the light bulb, without having incurred any research and development costs. In contrast to nonexclusive goods are exclusive goods. Returning to the example of Edison's apple, if Edison locks his apple in his refrigerator he can prevent Bell from consuming the apple. Therefore, Edison has excluded Bell from eating his apple.

These two characteristics of public goods create a free rider problem. The free rider problem occurs when people can enjoy the labor of others without paying for it. The patent system was created to resolve the free rider problem and other problems inherent with public goods such as inventions. [5]

To better illustrate the free rider problem and the benefits of the patent system, let's return to Edison's light bulb. Suppose Edison invests a great deal of time and a million dollars to research and develop the light bulb. Excited with his discovery, Edison announces it to the world and begins to manufacture light

[5]Id. at 58.

bulbs to sell to the public. In the absence of a patent system, Edison's competitor, Alexander Graham Bell, purchases a light bulb. Bell then reverse engineers the light bulb at a cost of $10,000. Bell then begins to sell light bulbs. Since Bell's research and development costs were lower than Edison's, he can sell the light bulb for less than Edison. Unable to recoup his research and development costs, Edison goes out of business. Faced with this scenario of events, inventors would not invent because competitors would free ride off of their labor. Furthermore, inventors would be discouraged from inventing because it would be difficult to recoup their research and development costs. This is especially true in the pharmaceutical industry. The pharmaceutical industry has high research and development costs because it is expensive to research, develop, and test new drugs before they can be sold to the public. In addition, once discovered drugs can be cheaply reproduced.

In order to resolve the public good problem, the government issues patents to inventors. The patent right to exclude others from making, using, or selling the patented invention resolves the public good problem by making patented inventions exclusive. However, inventions are still nonrival goods despite the patent. The fact that inventions remain nonrival is not a problem as long as the inventor can exclude others from unlawfully appropriating his invention. Competitors can no longer free ride off of an inventor's labor because the inventor can exclude the competitor from selling the patented invention.

The patent system does more than just resolve the public good problem. The patent system also encourages socially beneficial activities which might not occur otherwise. Patents provide inventors with incentives to invent. Without a patent, an inventor will not invest the time and resources necessary to create new inventions and explore unknown technologies because he will not be able to recoup his costs. If he cannot exclude others from making his invention he will be unable to make enough profit to recoup his costs. However, with a patent the inventor is adequately rewarded for his labor. He can exclude others from unlawfully appropriating his hard work and make enough profit to recoup his research and development

costs. In addition, the reward of making profits beyond his costs provides an incentive to continue to invest in research and development.

Patents also provide an incentive to disclose one's research. Part of the bargain made with the government in exchange for the patent right is to fully disclose one's invention. By disclosing an enabling disclosure, the patent system increases society's collective body of knowledge. Other inventors can then advance technology by referring to the growing body of knowledge society possesses.

Finally, patents provide the incentive to design around patents. Initially this may seem like an improper incentive. It would seem unfair to encourage people to engineer around a patented invention because it appears to be cheating. However, this is not the case because even a design around adds to society's collective knowledge. A design around may yield more efficient processes based upon the knowledge disclosed in a patent. In addition, the opportunity to design around encourages competition which will result in a more efficient marketplace.

One disincentive of the patent system is that it may temporarily slow the progress of science. Since the twenty-year patent grant prevents others for making, using, or selling the patented invention, other inventors will be discouraged from improving the patented technology if they will be unable to profit from their work. These inventors may wait until the patent expires before they invest the time and money into further research. This may not be a legitimate concern though because competitors may be able to license the patented technology. After obtaining a license, they are free to use the patented technology.[6]

[6]Id. at 62

The American Experience

The United States patent system finds its origin in the United States Constitution. Article I, Section 8, Clause 8 of the Constitution states that Congress shall have the power: "[t]o promote the Progress of Science and useful Arts by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writing and Discoveries". Shortly after the Constitution was ratified, the First Congress enacted the Patent Act of 1790 which authorized the United States government to issue patents. The 1790 Patent Act had two requirements for patentability, novelty and utility. In 1850, the Supreme Court added the modern day equivalent of the nonobviousness requirement when it decided *Hotchkiss v. Greenwood*[7].

In the past, the Supreme Court has not treated patents consistently. From 1890 to 1930, the Supreme Court treated patents favorably. However, the courts have not always treated patents favorably. From 1930 to 1950, the Supreme Court approached patents with suspicion for their monopolistic characteristics and their cost to society. During this time, the courts repeatedly struck down patents and continuously raised the bar of patentability. For example, in *Cuno Engineering Corp. v. Automatic Devices Corp.*[8], the Court required that inventions demonstrate a "flash of genius". The Supreme Court's hostility towards patents is best summarized by Justice Jackson's dissent in *Jungerson v. Ostby*[9] in which Jackson wrote, "the only patent that is valid is one which this Court has not been able to get its hands on."[10]

In the face of such hostility, the patent bar drafted the 1952 Patent Act to return the requirements of patentability to standards similar to the 1890 Patent Act. The 1952 Patent Act requires that an invention demonstrate utility, novelty, and nonobviousness. In a move to make the adjudication of patents more consistent and to prevent forum shopping, the United States Congress established the Court of Appeals for

[7]Hotchkiss v. Greenwood, 52 U.S. (11 How.) 248 (1850).
[8]Cuno Engineering Corp. v. Automatic Devices Corp., 314 U.S. 84 (1941).
[9]Jungerson v. Ostby, 335 U.S. 560 (1949).
[10]Id. at 572.

the Federal Circuit (Federal Circuit) in 1982. Today, all patent appeals from federal district courts are heard by the Federal Circuit.[11]

After being passed into law, the 1952 Patent Act was codified in Title 35 of the United States Code. The utility requirement is found in 35 U.S.C. Section 101. The requirement that an invention demonstrate utility has a low threshold. In order to have utility, an invention must demonstrate practical utility. The requirement that an invention be novel is found in 35 U.S.C. Section 102. To be novel, an invention must be new. To show that an invention is novel, a single piece of prior art cannot contain all of the invention's claim limitations. The nonobviousness requirement is found in 35 U.S.C. Section 103. The requirement that an invention be nonobvious was enacted to exclude minor improvements in existing inventions from being patented. If an invention is found to be obvious, all the claim elements must be found in a group of prior art sources. In addition, there must be a motivation to combine the group of prior art sources. Furthermore, there must also be the reasonable likelihood of success in combining the collection of prior art sources.

Brief Overview of Genetics

What is DNA?

In 1953, James Watson and Francis Crick discovered the molecular structure of deoxyribonucleic acid, or as it is commonly known, DNA. DNA is a long polymer chain that forms the basis of life. It is frequently described as the "blueprint" for nearly all organisms because DNA provides the instructions for life. It is based upon the information contained in DNA that some cells in the human body develop into bone cells while other cells differentiate into skin cells[12]. It is by reading the instructions contained in DNA that all

[11] Chisum, *supra* note 2, at 22.

[12] Daniel L. Hartl, et al., Genetics: Analysis of Genes and Genomes 2 (2001).

the cells of the human body are able to reproduce and differentiate in order to collectively form the human body.

DNA is a large molecule. It is comprised of two long chains which lie parallel to each other much like a ladder. Each side of the ladder is comprised of a deoxyribose sugar chain. Each step represents a base pair. The DNA "ladder" twists around to form a double-stranded helix.

Another way to organize the DNA strand is to divide it into nucleotides. In referring to our ladder metaphor, a nucleotide would comprise a rung in the ladder. In other words, the ladder's side and step. Each nucleotide contains the five carbon sugar, deoxyribose. In addition to containing deoxyribose, each nucleotide also contains a chemical constituent known as a base. There are four different bases found in DNA. They are: adenine (A), cytosine (C), guanine (G), and thymine (T). Biologists frequently use the letters A, C, G, T, as a short hand for describing each nucleotide base.

Another unique characteristic about DNA is that the two chains are complementary. Each chain is linked to the other by its nucleotide bases. The two complementary nucleotides, one from each chain, are called nucleotide base pairs. Each nucleotide has a specific complement. Thus, adenine bonds only with thymine, and cytosine bonds only with guanine. Due to this unique characteristic of DNA, if a scientist is given one strand of DNA she an easily determine its complement. For example, given GATC, the scientist knows that the complement is CTAG.

DNA is used by a cell to manufacture proteins. DNA contains the instructions for making protein. Based upon the instructions contained in DNA, a cell might produce insulin or human growth hormone. The first step in manufacturing proteins is to translate the DNA instructions. The cell translates DNA by reading groups of three nucleotide bases. These groups of three nucleotide bases are called codons. There are sixty-four different codons. However, there are only twenty different amino acids. The reason for the greater number of codons to amino acids is explained by DNA's degenerate nature. In other words, more than one

codon will encode for a particular amino acid. For example, the codons GAA and GAG both encode for the amino acid glutamic acid. The degenerate nature of DNA is a protective measure against mutations. If, for example, GAA mutated into GAG (a change of one nucleotide from A to G) there would be no disruption in translating the DNA sequence as both GAA and GAG specify glutamic acid.[13]

Each codon is translated by a cell to produce a complementary strand of messenger RNA (mRNA). The mRNA is nearly identical to the DNA codons except that thymine is replaced by uracil. The mRNA also differs from the DNA strand in that it is shorter. The mRNA strand is shorter than the DNA strand because the mRNA strand contains instructions for making only one protein whereas DNA contains the instructions for making all proteins and large stretches of non-coding information. After being produced, the mRNA leaves the cell's nucleus and attaches to a ribosome. The ribosome will read the mRNA codons and assemble the protein. As the strand of mRNA is read, the ribosome assembles a chain of amino acids which mirrors the instructions contained in the mRNA. This chain of amino acids is known as a protein. After the protein is assembled, it is released by the ribosome into the cell.

Illustrative Uses for DNA Sequences

A high degree of importance is placed on biotechnology patents because a patent provides some assurance that a biotechnology company will be able to recoup its high research, development, and government testing costs. Due to the high degree of importance placed on biotechnology patents and the emergence of DNA based technologies, it should not come as no surprise that inventors have sought patent protection for DNA sequences.

When genetics was in its infancy, there was a great deal of difficulty in identifying therapeutically signifi-

[13]Neil A. Campbell, Biology 302 (1996).

cant DNA sequences. Even if a therapeutically useful DNA sequence was found, one was still faced with the difficult task of sequencing that strand of DNA. At the time, scientists would isolate a therapeutically useful protein. Since the protein's blueprints were to be found in a DNA sequence, the scientists could work backward from the protein structure to the DNA structure. Thus, the scientist would isolate the protein and then sequence the protein's amino acid sequence. Using the amino acid sequence, the scientist could get a rough approximation of the correlating codon sequence. The codon sequence could then be interpreted as the DNA sequence encoding for the protein. The problem with this method of sequencing DNA is that it is time consuming and inaccurate. The degenerate nature of DNA makes it difficult to determine the exact DNA sequence starting with the protein.[14]

Initially, DNA sequence patents were sought for the particular DNA sequence necessary as part of an invention. For example, suppose an inventor realized that anemic patients could be effectively treated with erythropoietin (EPO), a protein which stimulates the production of red blood cells. In addition, suppose she had identified, isolated, and purified the DNA sequence which encoded for EPO[15]. Furthermore, suppose she had discovered a means to produce EPO recombinantly[16]. Recombinant DNA technology involves inserting the EPO DNA into a microorganism's DNA. The microorganism will read the EPO DNA as its own and express the EPO DNA. As a result, the microorganism will manufacture human EPO. The human EPO is then harvested for sale. Having identified the EPO DNA sequence and its necessity in manufacturing EPO, the inventor would want to secure patent protection for the EPO DNA sequence[17].

In addition, the inventor might also seek patent protection on her genetically modified microorganism which

[14] Joseph P. Pieroni, *The Patentability of Expressed Sequence Tags*, 9 Fed. Circuit B.J. 401 (2000).

[15] DNA is comprised of a series of nucleotides which are translated by a cell through a series of cellular processes to ultimately manufacture a protein.

[16] To produce a protein recombinantly, the protein's DNA sequence is inserted into a micro-organism. The genetically modified micro-organism, not suspecting that its DNA is different, manufactures the proteins encoded by its modified DNA. In addition to producing its indigenous proteins, the micro-organism also produces the protein encoded by the foreign strand of inserted DNA. With regard to the EPO example, a micro-organism would have EPO DNA inserted into its genome. It would then express the EPO DNA to produce the EPO protein. The EPO protein would then be harvested.

[17] See United States Patent No. 4,703,008 entitled, "DNA Sequences Encoding for Erythropoietin" issued on October 27, 1987.

produces EPO. She could also seek patent protection for the uses of recombinant EPO or of EPO DNA. Ever since genetically modified organisms were created in the lab, patent applications on these organisms have been filed with the United States Patent and Trademark Office. Eventually, the courts had to address the question as to whether or not these genetically modified living organisms could be patented. In *Diamond v. Chakrabarty*[18], the Supreme Court of the United States decided that product claims directed to genetically altered microorganisms were permissible. What has not been clearly determined is whether the DNA sequence used can be granted patent protection as well.

The significance of this question has increased now that a DNA sequence can be sequenced directly without first analyzing its corresponding protein. In order to sequence DNA, a series of enzymes are used which have the ability to cleave DNA at specific base pairs. First, the DNA strand is broken into smaller fragments using an enzyme called, endonuclease. For example, the DNA strand can be broken into three fragments. Each fragment is then radioactively labeled at the same end, called the 5' end. The 5' end is radioactively labeled because it serves as a point of reference. In a five nucleotide long sequence, the 5' end can be thought of as position 0. Unknown nucleotides reside at positions 1, 2, 3, 4, and 5. The radioactively labeled fragment is then exposed to a DNA cutting enzyme which is nucleotide specific. For example, enzyme A will cleave the DNA fragment at the adenine nucleotide. After exposing the DNA fragment to enzyme A, the cleaved fragment is separated by length. The fragment is then measured from the radioactively labeled 5' end. Let's say that after being treated with enzyme A, the DNA fragment is three nucleotides long. In other words, the DNA fragment has been cleaved at position 3. Since enzyme A only cuts at an adenine nucleotide, we know that the nucleotide at position 3 is adenine. The process is repeated with nucleotide specific enzymes for cytosine, guanine, and thymine to uncover the entire DNA sequence. The sequences of the three fragments are put together to determine the sequence of the entire DNA strand. Since DNA strands can be billions

[18]Diamond v. Chakrabarty, 447 U.S. 303 (U.S. 1980).

of nucleotides long, the process has been automated by using computers. The introduction of sophisticated software and fast computers has accelerated the rate at which DNA strands can now be sequenced.[19]

The conclusion of the human genome project ahead of schedule is a testament to the relative ease of sequencing DNA today. With today's advanced DNA sequencing technologies, there is no need to first identify a protein in order to work backwards to identify the accompanying DNA sequence. Unfortunately, scientists are now confronted with the problem of identifying the protein which correlates to the sequenced DNA. A further complication is that a large portion of the genome does not encode for any proteins, but represents genetic "noise".

What has resulted from these advances in technology is the ability of scientists to identify expressed sequence tags (ESTs) which are simply strands of DNA that have been decoded. ESTs can currently be used as DNA probes, but their utility will increase dramatically if the EST encodes for a therapeutically useful protein. The difficult legal question which has now arisen is whether or not DNA sequence patents should be permitted. Currently, biotechnology companies are filing vast numbers of EST patent applications in an attempt to claim patents on DNA sequences, and in particular patents on human DNA. This mad dash to the patent office is analogous to a frenzied land grab. In the rush to patent segments of the human genome, biotechnology companies are not taking the time to determine what their DNA sequences encode for, if anything at all. Companies are rushing to patent uncharacterized DNA sequences in a gamble that what they are claiming is valuable. Furthermore, by claiming DNA sequences first these companies are able to bar their competitors from using their patented DNA sequences. [20]

The question that this paper will address is whether or not DNA sequence patents are permissible under the

[19] James L. Gould and William T. Keeton, Biological Science, 264 (1996).
[20] Pieroni, supra note 14, at 403.

United States patent laws. In particular, this paper will argue that DNA sequence patents are impermissible because they do not constitute patentable subject matter as DNA sequence patents fall under the product of nature exception to patentable subject matter.

What is Patentable Subject Matter?

In order for an invention to be eligible for patent protection, it must meet several statutory requirements under 35 U.S.C. One of the requirements is that an invention fall within one of the categories of patentable subject matter as described in Section 101[21]. In addressing patentable subject matter, 35 U.S.C. Section 101 states in part: "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title."[22] A basic interpretation of Section 101 yields two general categories of patentable subject matter: (1) Products; and (2) Processes. Product claims can be separated into the three sub-categories consisting of: (1) machines; (2) manufactures; and (3) compositions of matter. Before 1980, the scope of patentable subject matter was considered to be relatively well defined. However, in 1980 the Supreme Court of the United States decided *Diamond v. Chakrabarty* to determine whether or not a man-made microorganism was within the realm patentable subject matter. In interpreting the scope of Section 101, the Supreme Court moved to expand the boundaries of patentable subject matter to include genetically modified micro-organisms.

In *Diamond v. Chakrabarty*, the inventor, Chakrabarty, filed a U.S. patent application claiming a human-made micro-organism as a product. Chakrabarty's human-made micro-organisms were bacteria genetically

[21]Donald S. Chisum, Chisum on Patents § 1.02 (2000).
[22]35 U.S.C. §101 (1952).

engineered to break down multiple components of crude oil. Chakrabarty's genetically modified micro-organisms have been found to be useful in cleaning up oil spills.

After filing his patent application, Chakrabarty's claims directed to the bacterium itself as an article of manufacture were rejected by the Patent Office Board of Appeals because it believed that the bacterium, as a living organism, was not patentable subject matter. Chakrabarty appealed the Patent Office Board of Appeals rejection, and his case was eventually heard by the United States Supreme Court.

In *Chakrabarty*, the Supreme Court only decided whether or not Chakrabarty's invention was patentable subject matter. They did not consider whether or not Chakrabarty's invention met the other requirements for patentability. The Supreme Court treated their decision as one of simple statutory interpretation.

> The question before us in this case is a narrow one of statutory interpretation requiring us to construe 35 U.S.C. § 101, which provides:
>
> > Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.
>
> Specifically, we must determine whether respondent's micro-organism constitutes a manufacture or composition of matter within the meaning of the statute.[23]

First, the court examined the plain language of the statute and stated that, "In choosing such expansive terms as manufacture and composition of matter, modified by the comprehensive any, Congress plainly contemplated that the patent laws would be given wide scope."[24] The Court then turned to the legislative history behind the 1952 Patent Act. Specifically, the Court examined the legislative history behind 35 U.S.C. §101. Contained within the Committee Reports for the 1952 Patent Act was Congress's intention that statutory subject matter "include anything under the sun that is made by man."[25] Drawing upon

[24]Id. at 308.
[25]S.Rep.No. 1979, 82nd Cong., 2d Sess., 5 (1952).

Congress's intention that the scope of patentable subject matter be expansive, the Court determined that Chakrabarty's microorganism was within the realm of patentable subject matter. The Court believed that, "... [Chakrabarty's] micro-organism plainly qualifies as patentable subject matter. His claim is ... to a non-naturally occurring manufacture or composition of matter... [Chakrabarty] has produced a new bacterium with markedly different characteristics from any found in nature and one having the potential for significant utility."[26]

The only limitation the Court placed on patentable subject matter were the longstanding limitations against patenting laws of nature, physical phenomena, and abstract ideas. Since Chakrabarty's micro-organism did not naturally occur in the world, it fell outside these exceptions to patentable subject matter.

Although the only issue decided by the Supreme Court in *Chakrabarty* was that genetically engineered micro-organisms were patentable subject matter, the message sent to the lower courts was that patentable "subject matter" should be construed expansively. By drawing upon the phrase "anything under the sun that is made by man" in coming to its decision, the lower courts interpreted *Chakrabarty* to indicate that the scope of patentable subject matter included "anything under the sun that is made by man"[27].

Even though *Chakrabarty* did not address whether or not DNA sequences were patentable subject matter, it presented a significant milestone in patent law. After *Chakrabarty*, the subject matter status of inventions became uncertain. Inventions previously considered not to be patentable subject matter before *Chakrabarty* might be construed as patentable subject matter after *Chakrabarty.* DNA sequences fell into this uncertain category of patentable subject matter.

Despite the Supreme Court's move to expand the scope of patentable subject matter in *Chakrabarty,* it should be reiterated that the court also upheld long standing exceptions to patentable subject matter. These excep-

[26] *Chakrabarty* at 309.

[27] See State Street Bank & Trust Co. v. Signature Financial Group, 149 F.3d 1368 (Fed. Cir. 1998) where the Court of Appeals for the Federal Circuit decided that methods of doing business were patentable subject matter.

tions to patentable subject matter include the "... laws of nature, physical phenomena, and abstract ideas"[28] These exception remain significant road blocks to patenting DNA sequences. Within the proscription against patenting laws of nature is the doctrine against patenting "products of nature"[29]. If DNA sequences are construed to be products of nature, then they fall outside the scope of patentable subject matter.

The Product of Nature Exception

The product of nature exception excludes from patentability inventions derived directly from naturally occurring products because these inventions are not made by man[30]. For example, a patent could not be obtained for shrimp which has been deveined and beheaded because the product claimed is essentially shrimp, a product of nature.[31]

The product of nature is derived from two sources. First, a product of nature cannot be patented because it is not a "machine, composition of matter, or manufacture" as described in 35 U.S.C. Section 101.[32] Even if the inventor is the first to discover or identify a product of nature, she may not patent it. However, the inventor may be granted a patent on a process for obtaining the product of nature (e.g. process for refining) or on a process for using the product of nature.[33]

Second, the exception is derived from the phrase "new and useful process, machine, manufacture, or composition of matter" in 35 U.S.C. Section 101. Based upon the term "new", it is believed that any product of nature simply discovered by man is not "new" because it was made by nature, not man. Hence, such

[28] *Chakrabarty* at 309.

[29] See Funk Brothers Seed Company v. Kalo Inoculant Company, 333 U.S. 127 (U.S. 1948).

[30] Construing products of nature as product not made by man allows the product of nature doctrine to conform to the Congressional intent that "anything under the sun that is made by man" is patentable subject matter.

[31] See Ex parte Grayson, 51 USPQ 413 (Bd. App. 1941).

[32] See U.S. Patent & Trademark Office, *Manual of Patent Examining Procedure* ß 706.03(a) (7th ed. July 1998) ("a thing occurring in nature, which is substantially unaltered, is not a "manufacture.").

[33] Donald S. Chisum, Chisum on Patents § 1.02[7] (2000).

products of nature cannot be protected by patents because they do not meet the requirements of Section 101.

Although the discoverer of a product of nature is barred from obtaining a product claim, the discoverer can obtain a process claim for obtaining the product of nature. For example, an inventor who discovered gold could not patent gold because gold is a product of nature. However, the same inventor could patent the process for extracting pure gold from gold ore. By granting a process patent, the inventor is granted monopoly rights in the process of extracting gold from gold ore. This in itself could be a very lucrative patent right. A patent on the process would also meet the aims of the patent system to reward and encourage innovation. The discoverer is encouraged by the reward of a patent monopoly to invent a process to extract pure gold from gold ore. In addition, if he so invents such a process he will be rewarded with a patent. Hence, there is no need to grant him a product patent on the gold as well since he is sufficiently rewarded by the process patent alone. If he is granted a product patent as well, the patent system may be over rewarding him for his contribution to society.

The added benefit of granting only a patent on the process is that other inventors have an incentive to design around the original inventor's process patent. By granting only a process patent, the patent system encourages competitors to develop new processes for extracting pure gold from gold ore. These design around processes fulfill another goal of the patent system which is to increase society's body of scientific knowledge. If the original inventor had been granted a patent on gold itself, future inventors who developed alternative processes for extracting pure gold from gold ore would still infringe the original inventor's patent on gold

itself. As a result, a product patent on gold would discourage innovation and work against the goals of the patent system.

The product of nature exception to patentable subject matter is best exemplified in the Supreme Court case, *Funk Brothers Seed Company v. Kalo Inoculant Company.* In *Funk Brothers*, the patent in question involved inoculants of the bacteria genus Rhizobium. It was well known in the prior art that Rhizobium bacteria had the ability of assisting leguminous plants in fixing nitrogen from the air[34]. Within the genus Rhizobium, there are six different species which infect the roots of leguminous plants and fix nitrogen from the air. No single species of Rhizobium can be universally applied to all plants. However, each species of Rhizobium is capable of infecting and fixing nitrogen in well-defined groups of plants (e.g. soy beans, but not garden beans). The only problem with species specific inoculation is that it is time consuming for a farmer to separately inoculate each of his crops. It would be more efficient for the farmer to use the same inoculants for all his different crops. The obvious solution to this problem of using a separate species of Rhizobium for each group of plants would be to inoculate all plants with all six species of Rhizobium. Unfortunately, this is not an efficient solution because the different species of Rhizobium have inhibitory effects on each other. What the inventor in *Funk Brothers* discovered was that there were no inhibitory effect when mixing some, but not all, species of Rhizobium. Upon making this discovery, the inventor was able to produce several mixed cultures of Rhizobium none of which had inhibitory effects on Rhizobium. The advantage of these mixed cultures over single cultures of Rhizobium was that the mixed cultures could be easily applied to several groups of plants (e.g. soy beans and garden beans). This solved the time consuming problem of having to treat each group of plants individually. In patenting his discovery, the inventor patented the process of making the mixed strains of Rhizobium bacteria as well as the mixed strains themselves.

[34]Fixing nitrogen from the air is a process by which nitrogen in the air is converted into a form that can be utilized by a plant. Plants without any assistance cannot utilize nitrogen gas.

In adjudicating the product claims, the Supreme Court found them to be invalid as products of nature[35]. In coming to its decision, the Court stated, "[The inventor] does not create [the] state of inhibition or of non- inhibition in the bacteria. Their qualities are the work of nature. Those qualities are of course not patentable. For patents cannot issue for the discovery of the phenomena of nature."[36] Since the inventor did no more than package a group of products of nature, the product claims were deemed invalid for lack of patentable subject matter.

Even though the court did not address DNA sequences in *Funk Brothers*, what it stated later in the opinion is of interest regarding the patentability of DNA sequences. Justice Douglas wrote,

> The qualities of these bacteria, like the heat of the sun, electricity, or the qualities of metals, are part of the storehouse of knowledge of all men. They are manifestations of laws of nature, free to all men and reserved exclusively to none. He who discovers a hitherto unknown phenomenon of nature has no claim to a monopoly of it which the law recognizes. If there is to be invention from such a discovery, it must come from the application of the law of nature to a new and useful end.[37]

[35]The inventor's process claims were not at issue in *Funk Brothers*. Therefore, despite losing his monopoly on the product claims, the inventor still retained the valuable monopoly rights to his process claims. As a result, the inventor's ingenuity was still rewarded by granting him a process patent.

[36]*Funk Brothers* at 130.

Based upon a *Funk Brothers* analysis, if DNA sequences are determined to be "manifestations of laws of nature" then they should not be deemed patentable subject matter. For if they are patented, the DNA sequences will cease to be "free to all men". However, *Funk Brothers* does not go so far as to discourage research and innovation in the field of genetics because the court explicitly provided an incentive to invent. "[T]he application of the law of nature to a new and useful end" can still be patented. This application of the law of nature, presumably, would include processes utilizing DNA sequences. Thus, for example, a process for isolating and purifying a DNA sequence would be patentable subject matter as would micro-organisms genetically modified to include recombinant DNA. In addition, an inventor could get a patent for uses of his DNA sequence or the products produced using his DNA sequence. For example, an inventor could get a patent on using EPO DNA to manufacture EPO recombinantly. In addition, the inventor could get a patent for using recombinant EPO to treat patients with blood disorders.

Funk Brothers, and the product of nature doctrine, would not impede the progress of genetic research. What the product of nature doctrine would achieve by not permitting DNA sequences to be patented would be to allocate the appropriate amount of incentives and rewards to biotechnological innovations. The patent system, by means of its grant of monopoly rights, inherently impedes the growth of science. This is an accepted element of the bargain the government makes with inventors in exchange for the inventor's scientific disclosure to the public. Since the monopoly right will impede the progress of science, it is critical for the patent system to appropriately reward inventors. If the patent system excessively rewards inventors, the concomitant impediment to scientific progress will outweigh the incentives to innovate.

Do DNA Sequences Fall Within the Product of Nature Exception?

Intuitively, it might appear that DNA sequences would fall under the product of nature exception. DNA, after all, is created by nature. Man played no part in designing the genetic code. In sequencing DNA strands, man is only exposing the nature's handiwork. This argument parallels the Supreme Court's argument in *Funk Brothers*.

Nevertheless, no court has definitively decided whether or not DNA sequences fall within the scope of patentable subject matter. In addition, to complicate matters there are exceptions to the product of nature exception. Hence, several products which appeared to be products of nature have been removed from the product of nature exception by the courts and moved back within the scope of patentable subject matter.

There are two lines of cases which will be examined below. One line of cases constricts the product of nature exception while the opposing line of cases attempts to expand the product of nature exception. The tension between these two lines of cases makes it difficult to determine where the boundaries of the product of nature exception lie.

Despite the uncertainty surrounding the product of nature exception, inventors have applied for DNA sequence patents. These inventors have relied upon the line of cases which limit the product of nature exception. Nevertheless, it is uncertain whether or not these patents, if issued by the U.S. Patent and Trademark Office, would be held valid in court[38].

In addition to the problem that *Funk Brothers* presents, another intuitive problem to patenting DNA is the fact that DNA resides in virtually all living organisms. For example, consider the DNA sequence encoding

[38]It should be noted that in litigation, patents issued by the United States Patent and Trademark Office have the presumption of validity. It is the burden of the patent challenger to provide evidence to the court that the patent in question is invalid.

for erythropoietin (EPO). EPO is a protein made by the human body which stimulates the production of red blood cells. It is effective in treating various blood disorders. The cells of most human beings carry the genetic code for EPO. It is an essential part of the human genome if people are to remain healthy. If a company is permitted to patent the DNA sequence for EPO they have the right to exclude anyone from making, using, or selling the DNA sequence for EPO. The inherent problem with such a product patent claim is that all healthy human beings would infringe this patent claim.

Creative patent claiming has gotten around this problem. Current DNA sequence patents only claim purified and isolated DNA sequences. By using the key phrase "purified and isolated", the patent will not cover the naturally produced DNA because cells do not naturally produce "purified and isolated" DNA sequences. Cells simply replicate all their DNA when they reproduce.

To illustrate, we return to the EPO example. If an inventor claimed the "purified and isolated DNA sequence of EPO" this claim would not cover healthy human beings because healthy people do not make or use the "purified and isolated DNA sequence of EPO". What human beings make and use in their everyday cellular processes is the entire human genome. There are no "purified and isolated DNA sequences of EPO" residing in human cells. In order to produce EPO, the human cellular machinery will access the entire human genome, but only utilize that part of the human genome which encodes for EPO.

This is an odd construct. Obtaining a patent on a "purified and isolated" DNA sequence is analogous to obtaining the right to exclude someone from making, using, or selling one volume of a multi-volume encyclopedia[39]. Using the encyclopedia analogy, Company A would produce the entire 26 volume encyclopedia to which it has no patent rights. Company B would then patent the rights to one volume, say volume D, of the encyclopedia. What arises is the odd result that if Company A produces the entire 26 volume encyclopedia, which includes volume D, it will not infringe Company B's patent on volume D[40].

[39]This example is for illustrative purposes only as printed matter falls outside the scope of patentable subject matter.

[40]This situation also raises doctrine of equivalence problems for DNA patent claims. Would a DNA sequence for EPO plus

Despite this odd result, this is the current interpretation of the law by the patent bar. The question whether or not a purified natural substance is patentable has been addressed in a series of cases which have determined that some natural substances are patentable while others are not. Due to this ambiguous result, it is difficult to discern whether or not a "purified and isolated" DNA sequence is patentable.

Purified Products of Nature

The issue of whether a purified natural substance could be patented was addressed as far back as 1874 in *American Wood Paper Company v. Fibre Disintegrating Company*[41]. The patent at the center of *American Wood Paper Company* claimed the product cellulose derived from wood pulp by a previously unknown process. However, the cellulose claimed was substantially similar to cellulose derived from a pre-existing method using rags instead of wood. Even though the new process produced a purer substance than the old process, the United States Supreme Court was not convinced in *American Wood Paper Company* that "a slight degree of purity [of two products] justifies denominating the products different manufactures..."[42] In so deciding, the Supreme Court invalidated the patent.

The Supreme Court's position that pre-existing substances which were only purified could not be granted product patents remained intact until an exception was carved out. In 1910, the Court of Appeals for the Seventh Circuit carved out an exception to the Supreme Court's "purity rule" when it heard *Kuehmsted v. Farbenfabriken of Elberfeld*[43].

The invention patented in *Kuehmsted* was aspirin, or acetylsalicylic acid. Acetylsalicylic acid had first

100 random nucleotides infringe a claim directed to the "isolated and purified DNA sequence of EPO"? In our encyclopedia example, this would be similar to company C producing a combined volume, for example, "D-E". Would volume "D-E" infringe a patent claim to only volume "D" in light of the fact that volumes "A-Z" do not infringe the patent to volume "D"?

[41] American Wood Paper Company v. Fibre Disintegrating Company, 90 U.S. 566 (U.S. 1874).

[42] Id. at 594.

[43] Kuehmsted v. Farbenfabriken of Elberfeld, 179 F. 701 (7th Cir. 1910).

been synthesized by one Kraut, but Kraut's synthesis yielded an impure product which could not be used therapeutically without harming the patient. Relying on Kraut's work, one Hoffman was able to purify acetylsalicylic acid so that it could be used therapeutically without harming the patient. In upholding the validity of Hoffman's patent, the Court of Appeals reasoned that because Hoffman's pure acetyl salicylic acid was therapeutically useful, it was presumed to be different from Kraut's therapeutically inaccessible acetyl salicylic acid. Since Hoffman's invention was different, the Court of Appeals decided it was new. Thus, Hoffman's invention was free to be patented.

Although the 1952 Patent Act was not the law in 1910, the 1952 Patent Act requires that inventions be "new and useful" to be eligible for patent protection. It is clear that Hoffman's invention was useful. It is not so clear that Hoffman's invention was new. Strangely, the court never addressed the issue of whether or not Hoffman's purified acetyl salicylic acid was really new. It only decided Hoffman's acetyl salicylic acid was different, and then presumed it to be new. It was certainly "new" in the sense that mankind was now in possession of a therapeutically accessible form of aspirin. However, was it really new given the fact that acetyl salicylic acid already existed?

In addition to *Kuehmsted,* the case most frequently cited to support the patentability of "purified and isolated" substances is *Merck & Company v. Olin Mathieson Chemical Corporation*[44]. In 1958, the United States Court of Appeals for the Fourth Circuit addressed the metes and bounds of the product of nature exception in *Merck*. The invention at the center of *Merck* was entitled, "Vitamin B(12)-Active Composition and Process of Preparing Same".

Prior to the discovery claimed by the patent, vitamin B(12) was unknown to man. What had been known was that patients who had pernicious anemia could mitigate the effects of their condition by consuming cow liver. For years the scientific community analyzed cow liver to determine what in cow liver was the

[44]Merck & Company v. Olin Mathieson Chemical Corporation, 253 F.2d 156 (4th Cir. 1958).

therapeutically active compound. For lack of a better term, scientists named this unknown therapeutic agent the "anti-pernicious anemia" compound.

After a considerable amount of chemical analysis, scientists at Merck isolated the "anti-pernicious anemia" compound in cow liver. They also discovered an alternate source of the "anti-pernicious anemia" compound. Merck scientists were able to harvest the "anti-pernicious anemia" compound from the fermenting eluent of certain microorganisms. After isolating and characterizing the structure of the newly found "anti-pernicious anemia" compound, the scientist renamed it vitamin B(12) for its chemical similarities to the vitamin B family.

Having discovered vitamin B(12), Merck filed for and obtained U.S. patent 2,703,302 ('the '302 patent") covering both the process of making vitamin B(12) and the actual chemical compound for vitamin B(12). Only the product claims were at issue in *Merck*[45]. A representative product claim reads:

> A vitamin B(12)-active composition comprising recovered elaboration products of the fermentation of a vitamin B(12)-activity producing strain of Fungi selected from the class consisting of Schizomycetes, Torula, and Eremothecium, the L.L.D. activity of said composition being at least 440 L.L.D. units per milligram and less than 11 million L.L.D. units per milligram.[46]

Prior to the appeal, the district court had determined that the product claims were invalid as products of nature. The Court of Appeals for the Fourth Circuit reversed. In reversing the District Court, the Fourth Circuit followed a line of reasoning similar to *Kuehmsted.* The Court of Appeals reasoned that the product of nature was the unpurified fermenting eluent which had no therapeutic value. However, Merck's purified fermenting eluent had therapeutic value. Thus, the court believed Merck's purified product, which was essentially vitamin B(12), was a different from unpurified fermenting eluent. Since Merck's purified product was different from the product of nature, the court reasoned that it could not be a product of nature.

[45]Since only the product claims were at issue in *Merck*, Merck still retained the valuable patent rights to the process of harvesting vitamin B(12) from micro-organisms.

The main weakness in the *Merck* decision is similar to weakness of the *Kuehmsted* decision. Can vitamin B(12) be considered "new" if it always existed in cow liver? In addition, is it necessary to grant Merck both product and process claims? Even without the product claims, Merck will still be able to profit handsomely from the process claims alone. In addition, Merck could have applied for a vitamin B(12) use patent. Merck could have patented the therapeutic use of their vitamin B(12) for treating pernicious anemia.

There are two interesting aspects of the courts decision in *Merck*. First, in coming to its conclusion that the purified fermentate was not a product of nature the court turned to the phrase "new and useful" contained in section 101. This was an appropriate focus of analysis for the court because it is from this phrase that the product of nature exception is derived. However, in interpreting the phrase "new and useful" the court substituted the patent terms "novelty and utility".[47]

The threshold for meeting the utility requirement for patentability is very low. Nearly all inventions meet the utility requirement. It is the Fourth Circuit's reliance on the patent requirement of novelty for the term "new" which is more interesting. The court's reliance of the novelty standard presents an interesting interpretation because the product of nature exception is not premised solely on the novelty requirement.[48] The product of nature doctrine simply states that products of nature are not patentable because they are made by nature, not by man. Furthermore, since products of nature existed in nature prior to man's discovery of them, they are not new and thus excluded from patentability.

The novelty standard requires a different analysis. Although the issue of novelty also addresses the question as to whether or not an invention is new, the question of novelty is answered by looking at the prior art. Roughly speaking, the prior art exemplifies man's entire body of scientific knowledge at the time of invention. In order to be novel, an invention must not be recited in one piece of prior art. For example, to demonstrate a lack of novelty, a single scientific journal article must describe how to extract vitamin B(12) from a fungal

[47]Id. at 164.
[48]Chisum, *supra* note 21, at § 1.02[8].

fermenting eluent.

The problem with using the novelty requirement to interpret "new" with regard to product of nature purposes is that no product of nature would be found in the prior art before it was discovered. In effect, using the novelty standard eviscerates the product of nature exception. The novelty standard also circumvents the purpose of the product of nature doctrine which is to prevent man from claiming "manifestations of [the] laws of nature".[49]

For illustrative purposes we can use vitamin B(12) as an example. According to the Fourth Circuit, in order for vitamin B(12) to be considered a product of nature it must lack novelty. To lack novelty, vitamin B(12) must be recited in a single prior art source. Before its discovery by Merck, vitamin B(12) was unknown and hence could not be found in any prior art source. However, vitamin B(12) has always existed as a naturally occurring substance in cow liver (i.e. a product of nature). Despite clear evidence that vitamin B(12) is a product of nature, the Fourth Circuit would permit a patent on vitamin B(12).

This approach nullifies the purpose of the product of nature doctrine. By using the novelty standard, the court never asks the question whether or not vitamin B(12) was made by man. The purpose of the product of nature doctrine is to prevent man from patenting what is made by nature and should thus be accessible to everyone. The Fourth Circuit's novelty analysis does not consider this.

The second interesting point about *Merck* is the product claim itself. In claim 1 recited above, vitamin B(12) is claimed only as a product of fermentation. Merck did not claim the vitamin B(12)chemical formula.

[49] *Funk Brothers* at 130.

This is a significant distinction because competitors could design around Merck's product claim if they could manufacture vitamin B(12) without utilizing the fermenting eluent of fungi. For example, a manufacturer who processed cow livers to obtain vitamin B(12) could sell its version of vitamin B(12) product without infringing Merck's product claims[50].

It is important for competitors to have the leeway to design around inventions because the progress of scientific innovation will continue. Competition will lead to new products or new processes which will benefit society. Furthermore, competition will encourage the discovery of new uses for existing products. If Merck had a product claim on the vitamin B(12) chemical formula, scientific innovation would be impeded because anyone who developed a new process for manufacturing vitamin B(12) would still be barred from making, using, or selling it.

The implications of patenting the chemical formula of a naturally produced substance is of particular relevance to patenting DNA sequences. DNA sequence product claims are for the chemical formula of the DNA sequence claimed. As a result, everyone is barred from making, using, or selling the particular DNA sequence claimed even if they develop a new process for isolating and purifying that particular DNA sequence. The problem with product claims covering the chemical formula of a product of nature is that they are too broad and excessively reward inventors who merely uncover what nature invented.

With cases such as *Kuehmsted* and *Merck* on one side of the product of nature debate, there are several cases which fall on the other side of the debate[51]. In addition to *Funk Brothers, General Electric Co. v. De Forest Radio Co.*[52] is representative of a court decision upholding the product of nature exception. The

[50]It is feasible that Merck could have an infringement claim under the doctrine of equivalence against its competitor in this example.

[51]See In re Marden, 47 F.2d 957 (finding uranium not patentable); In re Marden, 47 F.2d 958 (finding ductile vanadium not patentable).

[52]General Electric Co. v. De Forest Radio Co, 28 F.2d 641 (3rd. Cir. 1928).

invention at the center of *General Electric* was the chemical element tungsten (W). General Electric was assigned U.S. Patent 1,082,933 (the '933 patent) for tungsten.

Prior to General Electric's invention, the scientific community believed that tungsten as found in nature was pure tungsten. In its natural form, tungsten is a highly brittle substance not suitable to be manufactured into filaments for light bulbs. What the scientific community did not realize at the time was that tungsten as found in nature was actually tungsten oxide (WO_3).

What the inventor, Coolidge, thought he discovered was a process to transform natural tungsten into a ductile form of tungsten. Coolidge's ductile tungsten could be easily manufactured into filaments for light bulbs. What Coolidge did not realize was that his process simply refined natural tungsten, or tungsten oxide, into pure tungsten (W). Coolidge's ductile tungsten, in reality, was simply tungsten metal. Essentially, what General Electric was claiming in their patent was ownership to the chemical element tungsten[53].
In deciding *General Electric*, the Third Circuit invalidated the product claims to tungsten as a claim directed to a product of nature. However, the court upheld the validity of the process claims. In coming to its conclusion regarding the product claims of the '933 patent, the court asked itself,

> If it is a natural thing then clearly, even if Coolidge was the first to uncover it and bring it into view, he cannot have a patent for it because a patent cannot be awarded for a discovery or for a product of nature, or for a chemical element...If it is not a natural thing but is a thing which Coolidge created possessing characteristics different from those given by nature... he is without doubt entitled to a patent for it.[54]

The Third Circuit determined that "[w]hat [Coolidge] discovered were natural qualities of pure tungsten.

[53]To illustrate the fact that this claim strikes at the heart of the "manifestations of [the] laws of nature", General Electric's patent would be analogous to claiming ownership to oxygen.

Manifestly he did not create pure tungsten, nor did he create its characteristics."[55] Thus, the Third Circuit found that tungsten was a product of nature. As a result, General Electric was not entitled to product patent claims for tungsten.

Later in the opinion the court added, "The fact that no one before Coolidge found it there does not negative its origin or existence."[56] This statement is in direct contrast to the Fourth Circuit's decision in *Merck*. The decision in *Merck* appears to be justified by the fact that vitamin B(12) was new because no one had discovered it before. However, the Third Circuit would disagree because vitamin B(12) had always existed in nature.

Is DNA Patentable Subject Matter?

As the cases discussed indicate, it is not entirely clear whether or not DNA sequences are patentable subject matter. What is clear is that processes for isolating DNA sequences are permissible as are product claims that use DNA sequences (such as Chakrabarty's genetically modified micro-organism). In addition, inventors could get patents for the therapeutic uses of their DNA sequence products.

The Supreme Court's decision in *Chakrabarty* indicates an intention by the court to expand the scope of patentable subject matter, but the product of nature doctrine still remains. Whether or not the product of nature exception will apply to DNA sequences depends upon how the courts view DNA sequences. If the courts analogize isolated and purified DNA sequences to aspirin or vitamin B(12), then DNA sequences would be moved outside the product of nature exception and into the scope of patentable subject matter.

[55]Id. at 643.
[56]Id. 643.

On the other hand, if DNA sequences are comparable to tungsten or "manifestation of laws of nature" then the product of nature exception would apply.

As the law is currently interpreted by patent practitioners, the product of nature exception to patentable subject matter is considered a technical problem related to drafting DNA sequence product claims. For the patent attorney, all that is necessary to get around the product of nature exception is to not claim a DNA in its naturally occurring form. In order to resolve this technical problem, a patent attorney will claim DNA sequences in an "isolated and purified" form. For example, Amgen's DNA sequence claim to EPO in United States Patent 4,703,008 reads, "A purified and isolated DNA sequence consisting essentially of a DNA sequence encoding human erythropoietin."[57]

Since DNA sequences do not exist in an isolated form, this excludes a cell containing an entire genome (which in turn could contain the DNA sequence for EPO) from infringing the patent claim. This interpretation of the patent law is supported by cases, such as *Kuehmsted* and *Merck*, which have affirmed the validity of patent claims to naturally occurring chemical compounds that have been isolated and purified. [58] Despite the prevailing view among patent attorneys, it is still uncertain if the courts will find DNA sequence patents within the scope of patentable subject matter.

DNA sequences have been described as molecular strands of genetic information.[59] Information which is so fundamental that it is akin to the natural laws of science. This fundamental information, in the words of *Funk Brothers*, is "part of the storehouse of knowledge of all men. They are manifestations of laws of nature, free to all men and reserved exclusively to none."[60] As manifestations of the laws of nature, DNA sequences should be free to all men. By unlocking the hidden secrets of the genetic code, scientists will be able to produce new medical therapies to treat a wide range of illnesses. It is these new therapeutic inventions,

[57]United States Patent 4,703,008, entitled "DNA Sequences Encoding Erythropoietin" (issued October 27, 1987), claim 2.

[58]Rebecca Eisenberg, *Re-Examining the Role of Patents in Appropriating the Value of DNA Sequences*, 49 Emory L.J. 783 (2000).

[59]Id. at 786.

[60]*Funk Brothers* at 130.

their uses, and the processes for making them which should be patented, not the DNA sequences used to implement these inventions.

Because DNA sequences represent such fundamental scientific information, patents on DNA sequences should not be permitted. Patents on DNA sequences should not be allowed because they will impede research and innovation in biotechnology just as patents on natural laws would. DNA sequence patents will erect barriers that prevent scientists from using patented DNA sequences in their research.[61] Society will be harmed as the introduction of new DNA based therapies are delayed because researchers are patiently waiting for DNA sequence patents to expire.

In addition, the impediments to biotechnological innovations will increase with arrival of rapid DNA sequencing technologies. Since the introduction of rapid DNA sequencing, a race to the patent office has begun. Companies are filing patents on DNA fragments as soon as they are sequenced. In their rush to patent DNA fragments, these companies do not take the time to determine what these DNA fragments encode for, if anything at all. Even if they are issued DNA sequence patents, these companies will neither have the time nor resources to determine what all their patented DNA fragments encode for. As a result, many DNA fragments will remain unexplored until patent expiration. Scientists will have no incentive to study patented DNA fragments because they will not be able to pursue any discoveries they make.[62] Furthermore, even if these companies determine what their patented DNA fragments encode for scientists will be discouraged from discovering alternative uses for these patented DNA sequences. Hence, the full therapeutic potential of many DNA sequences will remain unstudied until the patents expire.[63]

In addition to preventing the patenting of natural laws, the product of nature doctrine has at its heart a desire to patent inventions which require human ingenuity. Although the 1952 Patent Act was legislated

[61] Arthur Allen, *Might Mice*, The New Republic, Aug. 10, 1998, at 17.

[62] Sara Dastgheib-Vinarov, *A Higher Nonobviousness Standard For Gene Patents: Protecting Biomedical Research From The Big Chill*, 4 Marq. Intell. Prop. L. Rev. 143 (2000). SEE PAGE 17.

[63] *Mapping Mankind*, The Economist, Oct. 24, 1992, at 18.

in part to neutralize the "spark of genius" test created by the courts[64], the requirement that inventions be nonobvious inherently retains a am implied requirement that inventions involve some small amount of ingenuity. After all, the fundamental nature of invention is that it requires human ingenuity however small.

The fundamental problem with the original DNA sequence patents is that the invention was the process of purifying a DNA sequence, not the DNA sequence itself. The inventor's ingenuity came into play in bringing the DNA sequence to light; in providing it to the world in a useable form. The inventor's ingenuity played no role in creating the DNA sequence itself as that was the work of nature alone. Even less ingenuity is required with expressed sequence tags (ESTs) which are sequenced en mass using rapid DNA sequencing techniques.

Although DNA sequences have been analogized to long polymer chains[65] and as a result should be treated similarly to synthesized polymers, this is not entirely correct. The analogy fails because an inventor's ingenuity plays a part in designing a polymer chain. A chemist will manipulate reaction conditions to produce a polymer with certain characteristics such as strength, durability, and flexibility. This is not the case with DNA. The inventor's ingenuity, once again, plays no part in designing the DNA sequence as this was the work of nature over thousands of years of evolution.

[64] 35 U.S.C. §100 (1952) states in part: "Patentability shall not be negatived by the manner in which the invention was made."
[65] See Amgen, 927 F.2d at 1200: "A gene is a chemical compound, albeit a complex one".

Conclusion

Patentable subject matter is statutorily defined in 35 U.S.C. Section 101 to include new and useful products (machines, manufactures, and compositions of matter) and processes. However, subject matter which fall outside the scope of Section 101 are products of nature.

There are two general arguments for excluding products of nature from patentable subject matter. First, is that products of nature are the "manifestations of laws of nature". As the building blocks of science, to grant ownership to these fundamental products would do more harm than good to scientific innovation.

Second, is the patent system's purpose in encouraging inventorship. An inherent aspect of inventorship is interaction of human ingenuity with the natural world. Products of nature are excluded from patentability because they would grant ownership rights to the natural world without any element of human ingenuity. These product of nature patents would reward inventors for nature's work.

This is the case with DNA. Man has played no part in creating DNA. It is nature which created and perfected DNA over thousands of years of evolution. What required man's ingenuity was isolating, purifying, and sequencing the DNA. These inventions deserve patent protection. After uncovering nature's handiwork, man then used his ingenuity and nature's DNA sequences to develop new inventions such as genetically modified micro-organisms. These inventions also deserve patent protection. What is not worthy of patent protection is the DNA sequence itself. These were created by nature and merely uncovered by man. DNA sequences should not be patented because in the words of *Funk Brothers* they are "free to all men and reserved exclusively to none".